

DMHAS OOC IRB REVIEWER CHECKLIST – EXEMPTION

Title of Study: _____ Date of Review: _____

Reviewer: _____

- 1) Will the research be conducted in an established or commonly accepted educational setting?
yes ☐ no ☐ If no, the study is not eligible for exemption. If yes, answer question a).

a) Will the research utilize normal educational practices? yes ☐ no ☐ If no, the study is not eligible for exemption. If yes, answer question b).

b) Will the research study education instructional strategies; or study or compare instructional techniques, curricula or classroom management methods? yes ☐ no ☐

In order to qualify for exemption the answer to both 3a and 3b must be yes.

- 2) Will surveys/interviews/questionnaires/other tests or instruments be used? ☐ yes ☐ no

a) If yes, will data collected from participants be recorded in such a way that participants can be identified directly or indirectly? ☐ yes ☐ no

b) If yes to a), could disclosure of the participants' responses outside the research setting place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability or reputation? ☐ yes ☐ no

If the answer to both 1a and 1b is yes, the study does not qualify for exemption

- 3) Will existing or archived data, documents, records or biological specimens be used? (existing means already collected at the time of the IRB application)? ☐ yes – complete questions a) and b)
☐ no – go to 2)

a) Is the source publicly available? ☐ yes ☐ no If no, answer b)

b) Will the information be recorded in such a manner that subjects can be identified?
☐ yes ☐ no If yes, study is not qualified for exemption.

The following are identifying links. If they are present in the data set the study is not qualified for exempt status. There may be other identifying links not listed below.

1. Names

2. All geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP Code, an their equivalent geographical codes, except for the initial three digits of a ZIP code if, according to the current publicly available data from the Bureau of the Census:

a. The geographic unit formed by combining all ZIP Codes with the same three initial digits contains more than 20,000 people.

b. The initial three digits of a ZIP Code for all such geographic units containing 20,000 or fewer people are changed to 000

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3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older.
4. Telephone numbers
5. Facsimile numbers
6. Electronic mail addresses
7. Social security numbers
8. Medical record numbers
9. Health plan beneficiary numbers
10. Account numbers
11. Certificate/license numbers
12. Vehicle identifiers and serial numbers, including license plate numbers
13. Device identifiers and serial numbers
14. Web universal resource locators (URLs)
15. Internet protocol (IP) address numbers
16. Biometric identifiers, including fingerprints and voiceprints
17. Full-face photographic images and any comparable images
18. Any other unique identifying number, characteristic or code

The study is exempt based upon the following criteria:

- ☐ (1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- ☐ (2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
- ☐ (3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- ☐ (4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
- ☐ (5) Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine:
- (i) Public benefit or service programs;
 - (ii) procedures for obtaining benefits or services under those programs;
 - (iii) possible changes in or alternatives to those programs or procedures;
 - or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

☐ (6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Signature of Reviewer

Date